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Comments of the Pharmaceutical Research and Manufacturers of America in Response to NIST's Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Docket No. 2023-0008)
February 6, 2024

I. Introduction

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the National Institute of Standards and Technology (NIST) Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights ("the Draft Framework").[1] PhRMA thanks NIST for holding a public webinar in December 2023 and for requesting stakeholder comments on the Draft Framework. PhRMA appreciates that the agency is seeking public participation on important innovation policy issues, as a transparent policymaking process is beneficial for all stakeholders.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA's member companies have invested more than $1.2 trillion in the search for new treatments and cures, including an estimated $100.8 billion in 2022 alone.[2] The biopharmaceutical industry is committed to working every day to discover and develop new treatments and cures for patients battling serious and life-threatening diseases such as Alzheimer's, heart disease, cancer, and, most recently, COVID-19, while also anticipating and preparing for the next pandemic. These new treatments and cures are made possible by the American system of intellectual property (IP) protections.

The U.S. biopharmaceutical industry relies on a well-functioning, science-based regulatory system, strong and reliable IP protection, and coverage and payment policies that support and encourage medical innovation to thrive. This system, in addition to the collaborative biopharmaceutical research ecosystem that includes both the private and public sectors, yields more innovative medicines than any other country in the world. The American biopharmaceutical research ecosystem is among our country's greatest strengths—in part due to policies enacted by Congress to ensure that federally funded inventions can move from the laboratory to the marketplace for the greater public good.

The Draft Framework misinterprets the Bayh-Dole Act of 1980 ("Bayh-Dole" or "the Act")[3] and uses a vague approach that is already causing uncertainty. As a matter of public policy, the Draft Framework is contrary to the purposes of Bayh-Dole and may instead cause outcomes contrary to its stated objectives. The Draft Framework ignores decades of policy precedent by encouraging federal agencies to explicitly consider the price of a product incorporating federally funded inventions when evaluating the statutory march-in criteria. The Draft Framework additionally imposes uncertainty in the context of a number of key issues which are discussed within our comments. If finalized in its present form, NIST's proposal would create an environment of uncertainty in the Act's licensing scheme that could discourage companies from investing funds in an already risky endeavor. The negative consequences of this uncertainty could send the U.S. innovation ecosystem back to a time before Bayh-

[1] 88 Fed. Reg. 85593–605 (Dec. 8, 2023).
[2] PhRMA, 2023 PhRMA Annual Membership Survey (2023), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/PhRMA_membership-survey_single-page_70523_es_digital.pdf.
[3] 35 U.S.C. §§ 200–12.

Dole when government-funded research sat on a shelf, undeveloped and unused. The significant negative consequences that may flow from this uncertainty, and from fundamentally undercutting the very purpose of Bayh-Dole, are offset by no measurable, practical or realistic gain for the American people or the U.S. innovation ecosystem.

Although PhRMA is focused on the Draft Framework's impact on the biopharmaceutical industry, the Draft Framework's negative impact would be felt broadly by all the other industries in which technical collaboration is important to the U.S. Government, including the green tech, energy, microchip and defense industries. The Government already struggles to successfully entice these industries to collaborate on important cutting-edge technologies, and this change in position and the uncertainty created by this Draft Framework will only make such collaboration more difficult to accomplish, to the detriment of the U.S. population.

In brief, PhRMA's comments are summarized as follows:

- The Draft Framework contradicts the purposes of Bayh-Dole and could well reverse the gains we have seen in innovation as a result of Bayh-Dole, causing reduced investment in public-private partnerships and minimal commercialization of federally funded inventions. The negative effects of the Draft Framework could have a ripple effect throughout the innovation ecosystem, ultimately reducing investment in small biotech companies and in the development of university inventions, and jeopardizing future benefits to the U.S. economy (Section II).

- The Draft Framework improperly incorporates price into the consideration of two march-in criteria, practical application and health and safety needs, contrary to Bayh-Dole's text and purpose (Section III). PhRMA rejects the premise that price should be a factor in the march-in analysis. Moreover, NIST's references to price are unclear and harmful to NIST's own stated goals for the Draft Framework (Section IV).

- The Draft Framework creates uncertainty in other interpretive issues beyond its consideration of price, including briefly discussing criterion 4 in a manner that fails to shed light on the scope of the domestic manufacturing requirement, and proposing a new definition of "shelving." The Draft Framework leaves key questions unanswered when discussing both issues, creating additional uncertainty for potential collaborators or investors (Section V).

- The factual scenarios cause further confusion, as they do not reach a conclusion on the proper determination of the march-in inquiry and invite unpredictable and inconsistent outcomes. If NIST cannot tell the public whether these simplistic fact patterns warrant the exercise of march-in rights, how could this Draft Framework inform industry and the public in real-world situations? The factual scenarios also fail to provide guidance along the full spectrum of technologies subject to the Draft Framework. The assumptions of the factual scenarios further limit their impact under the necessary totality-of-the-circumstances test that applies to the march-in analysis (Section VI).

We note, as a threshold matter, that NIST states one of the intended goals of the Draft Framework is to "[e]ncourage the consistent and predictable application of the Bayh-Dole Act's march-in authority."[4] NIST's goal implies that application of Bayh-Dole has previously been inconsistent and unpredictable, which is not the case. Since Bayh-Dole's enactment, the scope of march-in rights has consistently been interpreted narrowly as an extraordinary remedy. Bayh-Dole has been heralded as a resounding success

[4] 88 Fed. Reg. 85594.

for decades, and NIST's Draft Framework jeopardizes that success by including considerations, such as price, that are contrary to the Act and create uncertainty likely to discourage potential partners.

II. The Draft Framework is Misaligned with Bayh-Dole Policy Goals and Will Cause Outcomes Contrary to its Stated Objectives

Congress passed Bayh-Dole with bipartisan support to incentivize the private sector to transform discoveries resulting from government-funded, early-stage research into useful products. Bayh-Dole established a uniform framework across the federal government to encourage technology transfer to the private sector that has facilitated timely and efficient commercialization of federally funded research. Bayh-Dole allows recipients of federal funding agreements, such as universities, to retain ownership of inventions and associated patent rights covering such discoveries, enabling them to license the patents and allowing private sector partners to further research and develop these inventions.

A. Bayh-Dole was Enacted to Remediate Underutilization of Federally Funded Inventions Caused by U.S. Government-Retention of All IP Rights, which Prevented Commercialization.

Prior to enactment of Bayh-Dole, the U.S. Government retained ownership of the patents on federally funded inventions—and only 5% of those patents were ever licensed for use in the private sector.[5] Bayh-Dole was enacted to remediate stagnant innovation as to federally funded inventions in the United States. Collaboration was further incentivized by The Federal Technology Transfer Act of 1986, which authorized federal laboratories to enter into cooperative research and development agreements (CRADAs) with private businesses and other entities. These policies have proven critical to maximizing taxpayer benefit from government-funded research, which is funded by taxpayer dollars because private firms do not focus as much on basic science research. This is because basic science has widespread benefits that an individual firm is unable to "capture," and as a result not enough early stage general research is produced through the private sector alone.[6] Although some initial medical discoveries may have their origin in the research laboratories at the National Institutes of Health (NIH) or federally funded academic medical centers, technology transfer is ultimately what allows these early stage discoveries to be developed and made available to improve public health through licensing and collaboration agreements with the private sector. According to the NIH Office of Technology Transfer, "technology transfer moves medical innovation from the benchtop through additional research and development, testing, regulatory approval, manufacturing, and finally to distribution as a medical product which will improve the health of everyone."[7]

Partnership and technology transfer between the government and the private sector is critical because each plays a fundamentally different but complementary role in the biopharmaceutical R&D ecosystem. Initial federal funding is key to incentivize the basic research necessary to identify nascent opportunities for further private investment. The private sector then builds on the initial research—at significant risk and significantly greater investment than the initial federal funding—to expand and

[5] U.S. Gov't Accountability Off., GAO-09-742, *Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions* (July 2009), https://www.gao.gov/assets/gao-09-742.pdf.
[6] Richard R. Nelson, *The Simple Economics of Basic Scientific Research*, 67 J.POL. ECON., 297–306 (June 1959); Dana Dalrymple, Scientific Knowledge as a Global Public Good: Contributions to Innovation and the Economy in National Research Council (US) Steering Committee on the Role of Scientific and Technical Data and Information in the Public Domain (2003), https://www.ncbi.nlm.nih.gov/books/NBK221876/.
[7] Nat'l Insts. of Health, *The NIH and Its Role in Technology Transfer*, https://www.techtransfer.nih.gov/nih-and-its-role-technology-transfer (last visited Feb. 2, 2024).

develop an early concept into a marketable product.[8] Although NIH plays an important role in fostering basic research in genomics, molecular biology, and other life sciences that have identified new disease mechanisms, these discoveries are far from fully developed therapies for patients. These discoveries only become fully developed therapies available to patients because a private industry member takes them up and invests heavily in them.

A rich body of research describes the complementary roles of the public and private sectors that are necessary to advance medical treatments based on early-stage research funded by the federal government. In 2001, the NIH concluded in a study for Congress that the biopharmaceutical industry was responsible for the discovery and development of 91% (43 out of 47) of all the top-selling marketed drugs in 1999.[9] A 2022 analysis of 363 drugs approved between 2011 and 2020 found that 90% originated in industry.[10] An analysis of the contribution of NIH funding to new drug approvals from 2010 – 2016 found that although NIH funding contributed to published research associated with every one of the 210 new drugs approved by the Food and Drug Administration (FDA) in those years, 90% of the NIH funding supported basic research related to the biological targets for drug action rather than the drugs themselves.[11] More recent studies show that, although basic research is important, 92% of patents underlying new medicines do not necessarily contain federal funding statements, and further, 90% of new medicines are derived from the private sector.[12] Thus, while patents may arise from basic research, such patents may not end up reflected in a medicine. Other research has found that, of 23,230 NIH grants awarded in the year 2000 that were linked to the reported patent filings of 18 FDA-approved therapies by 2020, NIH funding totaled $0.670 billion, whereas private sector funding totaled $44.3 billion.[13] The research reflects that the disparate funding between the public and private sectors is a feature of allowing each sector to perform the role it does best in the ecosystem with federal funding: the public sector performs basic research to identify nascent concepts, and the private sector contributes the technical expertise and takes the significant, and necessary, financial risks to bring the initial research to fruition in the marketplace.

Indeed, the framework that Bayh-Dole created has fueled innovation and fostered public-private collaboration that is critical to meeting public health needs, such as responding to the COVID-19 pandemic. As a result of the innovation engine Bayh-Dole created, from 1996 to 2020, technology transfer has contributed $1.9 trillion to the U.S. economy, created 6.5 million jobs and helped to form 17,000 startups.[14] The large majority, 73% of university licenses over this period, have been to startups

[8] *See, e.g.*, Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* (Apr. 2021), https://www.cbo.gov/publication/57126 (discussing the complementary relationship between public and private R&D spending).
[9] DEP'T OF HEALTH AND HUMAN SERVS. & NAT'L INSTS. OF HEALTH, NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected (July 2001).
[10] Duane Schulthess, et al., *The US Ecosystem for Medicines* (Mar. 22, 2023), https://vitaltransformation.com/wp-content/uploads/2023/03/Where-do-new-medicines-originate_FINAL-HS-BIO-approved-2023_03_22-v3.pdf.
[11] Ekaterina G. Cleary, et al., Contribution of NIH funding to new drug approvals 2010-2016, 115 PROCEEDINGS OF THE NAT'L ACAD. OF SCI. OF THE U.S. OF AM., 2329–34, (Mar. 6, 2018) https://doi.org/10.1073/pnas.1715368115.
[12] Gwen O'Loughlin & Duane Schulthess, *March-in rights under the Bayh-Dole Act & NIH contributions to pharmaceutical patents*, VitalTransformation, at 8 (Nov. 30, 2023), https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf.
[13] Duane Schulthess, et al., *The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals*, VitalTransformation (Sept. 3, 2022), https://vitaltransformation.com/2022/09/the-relative-contributions-of-nih-and-private-sector-funding-to-the-approval-of-new-biopharmaceuticals/.
[14] Association of University Technology Managers, *Driving the Innovation Economy: Academic Technology Transfer in Numbers* (2022), https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf.

and small companies. Since 1980, more than 200 new medications and vaccines have been developed through various kinds of public-private partnerships.[15] Several studies have demonstrated that increases in NIH-funded basic research results in increased private R&D investment and innovation.[16] One study found that in the decade following an increase in NIH funding, private R&D spending grew by about eight times as much as the increase.[17] Another study found that each $10 million increase in NIH funding resulted in private sector investment and innovation reflected in a net increase of 2.7 patents.[18] Data from the decades following Bayh-Dole clearly reflect that the innovation ecosystem works because the private sector is willing and able to take on the difficult and risky task of developing early stage research into technology available to the American public.

B. The Draft Framework Would Discourage Biopharmaceutical Companies from Investing in Government-Funded R&D, and Companies Could Instead Prioritize Projects that Present Less Uncertainty

The biopharmaceutical industry's unique role in the research ecosystem is to utilize its scientific and industrial expertise and invest at risk to build upon and further advance basic science research to determine if safe and effective treatments can be developed and ultimately made available to patients. The federal government cannot research, develop, and manufacture vaccines and other new treatments without the resources, scientific expertise, R&D, manufacturing, technological platforms, and financial investment from private sector biopharmaceutical companies. This fact is supported by the recent analysis mentioned earlier which showed that 92% of medicines approved by the FDA between 2011 and 2020 have no mechanism of action or composition of matter patents with a government interest statement or federally funded co-development program in connection with them.[19] Across this time period, there were only 5 out of 361 pharmaceutical products in which all available mechanism of action and composition of matter patents included a government interest statement and could be subject to march-in rights. [20]

By scrutinizing pricing on biopharmaceutical products that include IP licensed under Bayh-Dole provisions, the government is adding significant risk and uncertainty to an already highly risky endeavor across the entire innovation ecosystem, without NIST acknowledging the limited universe of products to which the Draft Framework could apply. Researching and developing a new medicine takes 10-15 years on average and costs $2.6 billion including the cost of the many failures. Only 12% of new molecular entities that enter clinical trials eventually receive FDA approval.[21] NIST's Draft Framework would reduce investment by the private sector generally, and more specifically would discourage investment in any technology based upon government funding, which is the exact opposite of Bayh-Dole's intended outcome.[22] If the private industry is unable to later recoup its significant investment to develop early-

[15] *Id.*
[16] Wendy Schacht, CONG. RSCH. SERV., RL32324, *Federal R&D, Drug Discovery, and Pricing: Insights From the NIH-University-Industry Relationship* (Nov. 30, 2012), https://sgp.fas.org/crs/misc/RL32324.pdf.
[17] Andrew Toole, *Does Public Scientific Research Complement Private Investment in R&D in the Pharmaceutical Industry?*, 50 J.L. & ECON. 81 (2007), https://doi.org/10.1086/508314.
[18] Pierre Azoulay et al., *Public R&D Investments and Private-Sector Patenting: Evidence From NIH Funding Rules*, 86 Rev. Econ. Stud. 117 (Jan. 2019), https://academic.oup.com/restud/article/86/1/117/5038510?login=true.
[19] *See supra* note 12.
[20] *Id.* at 17.
[21] Joseph A. DiMasi, et al., *Innovation in the pharmaceutical industry: new estimates of R&D costs*, 47 J. HEALTH ECONS. 20–33 (Jan. 29, 2016).
[22] *See* Letter from Sen. Thom Tillis to President Joseph R. Biden (Dec. 20, 2023), at 1 ("The threat that government agencies will 'march-in' and seize patents if prices exceed a vague and undefined threshold undermines the certainty
(continued…)

stage discoveries and bring them to the market, the private industry will not invest, causing innovation to stagnate, which Bayh-Dole was designed to remediate. Such negative effects would not only harm the development of university inventions but would cause a ripple effect throughout the biopharmaceutical research and development ecosystem, with a disproportionate impact on investment in startups and small businesses, including small biotechnology companies, which rely on partnering with federally funded research facilities to obtain venture capital or industry investments. Further, the Draft Framework also runs counter to the goals of the Biden Administration's programs, such as the Biden Cancer Moonshot, which are designed to stimulate development of innovative treatments in part through public-private partnerships.

Policy proposals to place pricing restrictions on the private sector as a condition of partnering with the government have been tried before with disastrous results for patients and taxpayers. In 1989, the NIH imposed "reasonable pricing" conditions in CRADAs between federal labs and outside parties to conduct research or development. The policy was revoked in 1995 after public meetings were held with companies, patient advocates and researchers after which the agency concluded that these pricing conditions significantly chilled collaboration between the public and private sectors.[23] In his announcement of the decision, then Director of the NIH, Harold Varmus, M.D., said, "[a]n extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with [Public Health Service] scientists without providing an offsetting benefit to the public." Dr. Varmus further said, "[e]liminating the clause will promote research that can enhance the health of the American people."[24] After the removal of the clause, there was a subsequent rebound in CRADAs.[25]

Thus, the retention of IP ownership by the federal government prior to Bayh-Dole, as well as the failed reasonable pricing clauses implanted in CRADAs in the early 1990s, have demonstrated that restrictive IP terms stymied willingness to enter into research agreements with the federal government. Further, including price controls in the march-in analysis framework ignores the reality that the U.S. Government and the public already receive the benefit of the investment in public-private collaboration. Bayh-Dole creates a framework that in exchange for an initial amount of federal funding—most often a small amount in the context of the overall investment to the bring the product to market—the U.S. Government receives a license that allows it to use the invention for research and other government purposes.[26] In addition, the U.S. Government has protection under its march-in rights if there is a failure to take steps to commercialize or otherwise make the subject invention available under the terms of the Act. Thus, price controls cannot be justified as necessary for the U.S. Government to receive a return on its investment—the Act already provides that. In sum, the inclusion of price in the march-in analysis, as described by the Draft Framework, could have a chilling effect on innovation developed through

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that innovators need to make investments and bring complicated new technologies to market.") (available at https://www.tillis.senate.gov/2024/1/tillis-criticizes-biden-administration-on-inconsistent-interpretation-of-the-bayh-dole-act).

[23] Nat'l Insts. of Health, *Reports of the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development* (1994), https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH_%20CRADA_Report_on_Reasonable-Pricing_Clause_1994.pdf.

[24] Press Release, NIH News (Apr. 11, 1995), https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf.

[25] Nat'l Insts. of Health, *The NIH Experience with the Reasonable Pricing Clause in CRADAs FY1990-1995* (Nov. 15, 2021), https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf.

[26] 35 U.S.C. § 202(c)(4).

partnerships with the federal government that will cause outcomes contrary to the purposes of Bayh-Dole and the stated goals of the Draft Framework.

III. Bayh-Dole's Text, Structure, History, and Purpose Confirms that Price is Not a Proper March-In Factor

The Draft Framework improperly includes price as a factor in two of the march-in criteria: (1) whether effective steps to achieve practical application have been or will be taken ("practical application" or "criterion 1") and (2) whether a health or safety need has been reasonably satisfied ("health or safety need(s)" or "criterion 2"). The consideration of price under either statutory criterion is contrary to Bayh-Dole's text, structure, history, and purpose, not to mention decades of NIH agency precedent—the only agency precedent available to guide proper interpretation of the Act. By injecting price into an analysis where it was not intended, the Draft Framework risks causing negative outcomes, such as inhibiting innovation and commercialization. As mentioned above, NIH's since-abandoned experiment of imposing pricing terms within its model CRADAs caused reduced private sector investment in developing early-stage discoveries, akin to the lack of innovation in the U.S. economy that created the need for the Act. Though the Draft Framework is presented as non-binding, it makes novel legal interpretations regarding the role of price in a march-in rights assessment under criterion 1 and criterion 2, thereby injecting needless and unacceptable risk to the continued success of Bayh-Dole in violation of the statute's language and purpose and contrary to the stated goals of the Draft Framework.

A. Price has Consistently Been Rejected as a Basis for March-In Under the Practical Application Criterion.

Bayh-Dole does not contain any language discussing price, whether in the goals of the Act, the relevant definitions, the basis for exercising march-in rights, or elsewhere.[27] The definition of practical application states that "the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."[28] Under criterion 1, a federal funding agency may march in if it "is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use[.]"[29] A product's price is not mentioned.

As several legal scholars have further explained, one would have to both wrongly take phrases and words out of context and not assign words their proper meaning for price to be considered under the practical application criterion.[30] Notably, "terms" and "price" are distinct legal concepts that statutes distinguish between, and the Act here clearly includes terms and not price.[31] Further, Bayh-Dole expressly sets out its goals in 35 U.S.C. § 200, including: "to promote the commercialization and public availability of inventions made in the United States by United States industry and labor." Reading price into the practical application criterion would be contrary to the goals set out in the Act, and contrary to the

[27] *See, e.g.*, 35 U.S.C. §§ 200–01, 203. Statutory interpretation begins with the text. *Lamie v. U.S. Tr.*, 540 U.S. 526, 534 (2004) ("The starting point in discerning congressional intent is the existing statutory text.").
[28] 35 U.S.C. § 201(f).
[29] 35 U.S.C. § 203(a)(1).
[30] Letter from Jonathan Barnett, et al., to Sen. Bernie Sanders, et al. (Sept. 28, 2023), at 5 (available at https://www.prnewswire.com/news-releases/former-officials-scholars-call-out-twisting-of-patent-laws-to-push-policy-agenda-301942355.html) (hereinafter "Barnett Letter"). *See also* Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, CTR. FOR LIFE SCIS. INNOVATION 30–31 (Mar. 4, 2019), https://www2.itif.org/2019-bayh-dole-act.pdf (discussing that interpreting practical application to include price controls is inconsistent with the intent of the Bayh-Dole Act).
[31] *Id.* (citing, for example, 47 U.S.C. § 335(b)(3)).

principle that a specific statutory section must be construed "within the overall statutory regime of which it is a part."[32]

The instances in which Congress has granted federal agencies authority to control pharmaceutical pricing provide further support that doing so in the context of the Bayh-Dole Act is improper. For example, under the Veterans Health Care Act of 1992, Congress granted explicit authority for a federal ceiling price to be imposed on pharmaceuticals purchased by certain federal agencies (VA, DoD, PHS and the Coast Guard).[33] If Congress intended for the Bayh-Dole Act to grant agencies authority to control subject invention pricing in government procurement, much less commercial pricing, past precedent instructs that Congress would have granted such authority *explicitly*. Injecting price into the Draft Framework's interpretation of the practical application criterion is again contrary to the text of the Act and also contrary to principles of statutory interpretation.

Further, and by its express terms, criterion 1 only applies to the contractor or assignee and *not* licensees. That is, to exercise march-in rights under this criterion a federal funding agency must determine that such "action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use[.]"[34] Since Bayh-Dole generally contemplates a model of technology transfer whereby a non-profit entity (e.g., a university) holds title to a patented subject invention and then licenses the rights under such patent to a licensee to commercialize the invention, it is informative that "licensee" is omitted in criterion 1. The text reflects that Bayh-Dole's purpose was not to include the commercial activities of the licensee within the scope of activities that define whether practical application has been met. This approach makes logical sense when applied in the real-world marketplace, as Bayh-Dole contractors are not in a position to control the ultimate price at which a licensee offered its products in the market. Indeed, criterion 1 reflects the goal of achieving the transfer of rights to an entity able to bring them to market, and that, once the transfer of rights to a licensee has occurred, with a commitment of the licensee to take steps to commercialize the subject invention, the requirements of criterion 1 are met.

Although the language of Section 203(a) generally contemplates that the government may exercise its march-in rights against contractors, assignees, *or* exclusive licensees, each criterion then defines its applicable scope from this menu of options. Criterion 1 applies only to the contractor or assignee (i.e. licensees are omitted from this criterion), whereas, notably, the other three march-in criteria do not similarly omit mention of licensees.[35] Where language is omitted from one section of a statute but included in another, that omission is significant and should be presumed to be intentional.[36] Thus, the omission of any mention of licensees in Section 203(a)(1) signals the correct interpretation of Section 203(a)(1) is that it does not apply to licensees.

Criterion 1 therefore clearly differs from the other three criteria, reflecting an intentional choice by Congress to protect against a failure of a contractor or assignee to take action to commercialize funded technology contrary to the purpose of the statute. Bayh-Dole was implemented to encourage licensing of

[32] *Id.* at 5–6.
[33] *See* Pub. L. No. 102-585.
[34] 35 U.S.C. § 203(a)(1) (emphasis added).
[35] *See, e.g.*, 35 U.S.C. § 203(a)(2) (providing a march-in right where action is necessary to alleviate health or safety needs not reasonably satisfied by "the contractor, assignee, or their licensees").
[36] *See Russello v. United States*, 464 U.S. 16, 23 (1983) (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)) ("'[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'").

inventions for commercial production—allowing the exercise of march-in rights in circumstances in which the contractor has already done so would be contrary to the purpose of the Act. Further, considering price under this criterion where the statute does not contemplate it is contrary to the law and the statutory purpose of the Act.

1. As Previously Acknowledged by NIST, the Statutory Purpose and Sponsor Statements Expressly Reject Price as a Factor for March-In

The statutory language and context in which Bayh-Dole was enacted are devoid of any implication that march-in rights could be used as a price control mechanism under any of the four statutory march-in criteria. Rather, the statutory purpose and post-enactment statements by the Act's sponsors demonstrate that these bases were narrowly conceived as preventing title holders from frustrating the fundamental purpose of Bayh-Dole by not commercializing the subject invention.[37] This narrow understanding is reflected in both early and final drafts of the bill. For instance, an early draft report from the Science and Technology Committee stated that march-in rights would be invoked only "when the invention is *not being used* and it appears that there is a public need to use the invention."[38] Further, the final Senate Committee report echoes this narrow understanding, stating that march-in rights were meant to benefit the public welfare by encouraging contractors or licensees to "commercialize the invention, thus making it available for public use."[39]

Following Bayh-Dole's passage, Senators Bayh and Dole have unequivocally stated that "Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research."[40] More broadly, Senator Bayh described that march-in provisions were included in the Act to address "fear [that] was expressed that some companies might want to license university technologies to suppress them because they could threaten existing products."[41] The goal of march-in rights, then, was to protect against non-use of a subject invention rather than to control the price of a commercialized product. Any attempt to re-characterize the legislative history as supporting price control regulation through the exercise of march-in rights, in Senator Bayh's own words, "flagrantly misrepresent[s] the Act's legislative history supporting Bayh-Dole."[42]

Indeed, NIST previously highlighted—consistent with the above referenced statements by Senators Bayh and Dole —in its march-in analysis in its 2019 Final Green Paper that "the government has interpreted reasonable terms to mean reasonable *licensing* terms. The original sponsors of Bayh-Dole have publicly stated that their intent was to ensure that products were licensed for reasonable terms rather than being used as a price control."[43] Further, in support of a textualist interpretation of the Act, the sponsors have stated that "[t]he ability of the government to revoke a license granted under the [Act] is

[37] *See* S. Rep. No. 96-480 at 28 (1979).
[38] *Id.* at 18–19 (emphasis added).
[39] *Id.* at 28.
[40] Sen. Birch Bayh, Sen. Bob Dole, *Our Law Helps Patients Get Drugs Sooner*, WASH. POST, (Apr. 11, 2002) (hereinafter "*Our Law*").
[41] Birch Bayh, Statement of Senator Birch Bayh to the National Institutes of Health at the Public Meeting on Norvir/Ritonavir March-in Request, 2 (May 25, 2004) (hereinafter "Sen. Bayh Statement") (available to access at https://www.techtransfer.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf (last accessed Feb.1, 2024)).
[42] *Id.* at 3.
[43] NIST Special Publication 1234, *Return on Investment Initiative for Unleashing American Innovation* (Apr. 2019) 30 https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf (emphasis added).

not contingent on the pricing of the resulting product or tied to the profitability of a company that has commercialized a product that results in part from [federally] funded research."[44] Under the practical application criterion, "[t]he law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product."[45] However, the level of activity required to deflect a march-in inquiry under this criterion could be satisfied even when commercialization has not yet been achieved. The plain text of the Act reflects that march-in cannot ensue under this criterion when a company has taken *or expects to take* "steps to achieve the practical application" of the subject invention.[46]

In the Draft Framework, however, NIST departs from its prior Green Paper analysis, the Bayh-Dole text, and its statutory purpose by including price in the practical application analysis. Although the statute and legislative context focus on whether the product embodying the subject invention has been commercialized, the Draft Framework newly and improperly states that, even with commercialization, practical application may not have been achieved: "If the contractor or licensee has commercialized the product, but the price or other terms at which the product is currently offered to the public are not reasonable, agencies may need to further assess whether march-in is warranted."[47] This proposed analysis directly contradicts the statute and the Act's purpose by stating that even if a goal of the Act has been achieved, e.g., commercializing a subject invention, a contractor, assignee, or licensee may still be subject to march-in rights.

Further, and instead of focusing on whether the terms of the license are reasonable, the Draft Framework focuses on the actions of the licensee and terms of the public's use of the product. The Draft Framework considers whether action may be needed to "protect the public against nonuse or unreasonable use of the subject invention," permitting "consideration of factors that unreasonably limit availability of the invention to the public, including the reasonableness of the price and other terms at which the product is made available to end-users."[48] Such consideration of the price the end-user pays contradicts the statute's text, which under criterion 1 focuses on the terms of the license. Not only does including price in the Draft Framework contradict the Act's text, but it also contradicts decades of clear agency precedent.

2. NIH Has Determined that Price is Not a Statutory Criterion for March-In

NIH is the only agency that has issued decisions, all of which were declined, in response to petitions to exercise its march-in authority in the over 40 years of Bayh-Dole's existence.[49] When interpreting the statutory definition of practical application, NIH has consistently found that price is not a consideration when determining whether the invention's benefits are "available to the public on reasonable terms."[50] NIH precedent states that a subject invention is available on "reasonable terms" when the terms of the license support the obligation to seek its approval by the FDA, manufacturing,

[44] *Id.* (quoting *Our Law*, *supra* note 40).
[45] *Id.*
[46] 35 U.S.C. § 203(a)(1) (emphasis added).
[47] 88 Fed. Reg. 85598.
[48] *Id.*
[49] The NIH decisions discussed in these sections are NIH responses to petitions for NIH to consider exercising its march-in rights. NIH has declined each one, meaning that NIH has never commenced a formal march-in proceeding in response to any of the requests to do so, in part because price is not an appropriate consideration in the question of practical application.
[50] 35 U.S.C. § 201(f).

availability to the public, and use by patients.[51] Further, NIH's analysis is consistent with the focus on the reasonable terms that the contractor or assignee offers in its license and *not* the terms on which the product is offered for sale.[52]

NIH has consistently found that the price at which a product is sold in the U.S. or pricing disparities found between the U.S. and other countries do not bear on any of the four statutory march-in criteria, repeatedly determining that the Act does not grant authority to control pricing of subject inventions.[53] Indeed, NIH's consistent position has been that "the extraordinary remedy of march-in is not an appropriate means of controlling drug prices. The issue of drug pricing has global implications and, thus, is appropriately left for Congress to address legislatively."[54] Congress has not done so and NIST's contrary guidance in the Draft Framework cannot and should not alter the longstanding interpretation of the Act. On several occasions, Congress has requested NIH and the U.S. Department of Health and Human Services (HHS) to hold public meetings on the issue of march-in rights and consider exercising march-in rights to lower drug prices.[55] NIH has consistently held its position that controlling prices is beyond the scope of its authority: "The NIH has authority to act directly or by contract to 'secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research.' As such, the NIH is a research institution not a drug manufacturer."[56] HHS has responded to such Congressional letters noting that "HHS will also continue to give petitions for the use

[51] Letter from Dr. Francis S. Collins to Dr. Andrew Goldman, ("*Xtandi I")*, NAT'L INSTS. OF HEALTH, 1 (June 20, 2016) (citing *CellPro, Norvir I* and *II,* and *Xalatan* when finding that "practical application is evidenced by the 'manufacture, practice, and operation' of the invention and the invention's 'availability and use by the public[.]'"); Dr. Harold Varmus, *Determination in the Case of Petition of CellPro, Inc.* ("*CellPro*"), NAT'L INSTS. OF HEALTH, 5 (Aug. 1, 1997); Dr. Elias Zerhouni, *In the Case of Norvir ("Norvir I")*, NAT'L INSTS. OF HEALTH, 5 (Jul. 29, 2004) (finding that the drug had reached practical application since it was on the market, available to patients, and being utilized); Dr. Elias Zerhouni, *In the Case of Xalatan ("Xalatan")*, NAT'L INSTS. OF HEALTH, 5 (Sept. 17, 2004) (finding that the drug had reached practical application as it was widely available for and utilized by patients); Dr. Francis S. Collins, *Determination in the Case of Norvir, Manufactured by AbbVie ("Norvir II")*, 4 (Nov. 1, 2013) (finding that Norvir still achieved practical application as an FDA-approved drug since 1995). All NIH march-in decisions are accessible at https://www.techtransfer.nih.gov/policy/policies-reports.

[52] *See* Letter from Dr. Lawrence A. Tabak to Mr. Robert Sachs and Mr. Clare Love, ("*Xtandi II*"), NAT'L INSTS. OF HEALTH, 2 (Mar. 21, 2023) (determining that "the *patent owner*, the University of California, does not fail the requirement for bringing Xtandi to practical application, as the drug is manufactured and on the market in the manner of other prescription drugs.") (emphasis added).

[53] *See Norvir I* at 1 (determining that the Petitioner's drug pricing argument did not warrant the exercise of march-in rights based on the "statutory and regulatory framework"); *Xalatan* at 1 (similarly determining that the pricing arguments put forth did not warrant march-in proceeding under the "statutory and regulatory framework); *Norvir II* at 6 (stating that the drug manufacturer's policies and pricing disparities between the United States and other countries does not trigger any of the four Bayh-Dole march-in criteria); *see also Xtandi I* (declining to exercise march-in rights because Xtandi is broadly available as a prescription drug, notwithstanding Petitioners' arguments that U.S. patients pay higher prices than those in other high-income countries).

[54] *Norvir I* at 5–6.

[55] *See, e.g.*, Letter from Sen. Elizabeth Warren, et al., to Sec'y Xavier Becerra (July 28, 2021), https://www.warren.senate.gov/imo/media/doc/2021.07.28%20Letter%20to%20Secretary%20Becerra%20re%20Drug%20Pricing%20Authorities.pdf; Letter from Sen. Elizabeth Warren, et. al., to Sec'y Xavier Becerra (Feb. 17, 2022), https://www.warren.senate.gov/imo/media/doc/2022.02.17%20Letter%20to%20Sec.%20Becerra%20on%20Xtandi%20March-in%20Petition%20(2).pdf; Letter from Sen. Elizabeth Warren, et al., to Sec'y Xavier Becerra (Jan. 10, 2023), https://www.warren.senate.gov/imo/media/doc/Bicameral%20Xtandi%20Petition%20Follow-up%201.10.23%20FINAL1.pdf.

[56] *Norvir II* at 5 (citing 42 U.S.C. § 284(b)(l)(F)).

of march-in rights due consideration."[57] Such correspondence does not reflect any change in the longstanding consideration that NIH has given to march-in petitions.

The Draft Framework includes questions to guide agency march-in analysis that directly contradict agency precedent. As part of the consideration for whether an agency should march in under the practical application criterion, the Draft Framework asks: "At what price and on what terms has the product utilizing the subject invention been sold or offered for sale in the U.S.?"[58] Such leading questions cause the type of uncertainty and unpredictability that NIST has stated it wants to avoid and is even contrary to its own interpretation of the issue in its Final Green Paper.

More problematically, NIH could be subject to legal challenges if it opted to follow the NIST Draft Framework, which is contrary to NIH's own prior decisions.[59] A sudden and unfounded reversal could be seen as arbitrary and capricious if NIH ultimately decides to recognize "price control" as a factor under §203(a)(1) or as an interpretation of "reasonable terms" under §201(f). Agencies may not change their rulemakings and guidance arbitrarily.[60] Indeed, an agency may not alter its prior interpretation of a statute without acknowledging the change and explaining it.[61] NIH has stated on several prior occasions that price control is not a statutory ground for the exercise of march-in rights under the Act.[62] The Act has not been amended since enactment to allow NIH to set, enforce, or control pharmaceutical drug pricing. Therefore, to suddenly claim that march-in rights convey the ability to enact pharmaceutical price controls, without any additional grant of statutory authority, could be viewed as an arbitrary and capricious change in position subject to challenge under the APA.[63]

Furthermore, a change to the long-standing statutory interpretation that price control is not a ground for the exercise of march-in rights could, without an additional grant of statutory authority, be struck down under the major questions doctrine. The Supreme Court has held that the major questions doctrine applies where an Agency claims an "unheralded power" representing a "transformative expansion in [its] regulatory authority" based on a "long-extant statute."[64] When this type of regulatory authority has significant economic and political consequences, the Supreme Court has found "a reason to hesitate before concluding that Congress" intended to confer such authority.[65] Such regulatory authority

[57] Letter from Sec'y Xavier Becerra to Sen. Elizabeth Warren (Nov. 15, 2021), https://www.warren.senate.gov/imo/media/doc/HHS%20Reply%20to%20July%2028%20Letter%20Regarding%20Prescription%20Drug%20Pricing.pdf.
[58] 88 Fed. Reg. 85599.
[59] It is also contrary to the clear and unambiguous language of the statute. *See, e.g.*, Letter from Sec'y Sylvia M. Burwell to Rep. Lloyd Doggett (Mar. 2, 2016), http://freepdfhosting.com/be7532cfc0.pdf. However, should NIH impermissibly depart from its prior interpretation of criterion 1 as the Draft Framework suggests, the discussion below would apply.
[60] 5 U.S.C. § 706(2)(A), (2)(E). Agencies also may not interpret a statute to expand its own authority where Congress has not clearly conferred such authority. *W. Virginia v. Env't Prot. Agency*, 597 U.S. 697, 721 (2022) (discussing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000)).
[61] *See, e.g., Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) ("When an agency changes its existing position, it . . . must at least 'display awareness that it is changing position' and 'show that there are good reasons for the new policy.'" (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009))).
[62] *See, e.g., Xalatan* at 5, *Norvir I* at 5, and *Norvir II* at 6.
[63] 5 U.S.C. § 706(2)(A).
[64] *See W. Virginia v. Env't Prot. Agency*, 597 U.S. 697, 724 (2022).
[65] *See, e.g., id*. at 725, 729; *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000).

is rarely conferred through "modest words," "vague terms," or "subtle device[s],"[66] particularly where an agency seeks to use this authority to make a "radical or fundamental change" to a statutory scheme.[67]

Here, the inclusion of price as a ground for exercising march-in rights represents an expansive interpretation of the march-in authority conferred by Bayh-Dole that is contradictory both to NIH's prior interpretation of this authority and the purpose of the statute. The statutory basis for this position is the sort of "vague" and "subtle" language insufficient to demonstrate explicit congressional intent to confer such authority; Bayh-Dole includes no mention of price as a basis for march-in, so the Draft Framework must rely on terms permitting march-in if "practical application" has not been achieved in a "reasonable" amount of time.[68] This interpretation would also carry significant economic and political significance given the number of sectors impacted, and the "global implications" NIH has previously cited when denying the use of march-in authority to address price concerns.[69] This change in position therefore represents the very kind of "radical or fundamental change" that the Supreme Court has struck down under the major questions doctrine.

A change in position to allow consideration of price as a ground for exercising march-in rights could also constitute a regulatory taking under the Fifth Amendment. Changing the interpretation of the Act after numerous companies have secured exclusive licenses and invested substantial resources in the commercialization of inventions could constitute a regulatory taking. To determine when a regulatory taking occurs, courts balance factors including: (1) the economic impact of the regulation, (2) its interference with investment-backed expectations, and (3) the character of the government action.[70] These factors weigh in favor of finding a regulatory taking. First, a decision by funding agencies to march in based on a previously-absent "reasonable pricing" standard would render exclusive licenses nearly valueless and significantly interfere with investment-backed expectations.[71] Second, in considering the character of the government action, the duration of the restriction is "one of the important factors that a court must consider."[72] The Draft Framework has no specified duration for the use of price as a grounds for march-in authority, and would therefore render the exclusive licenses nearly valueless for the life of the patent, weighing in favor of finding a regulatory taking. NIST has never promulgated formal regulations on march-in rights such that licensees have received notice of being held to a "reasonable pricing" standard when agreeing to commercialize inventions. In fact, the Draft Framework contradicts previous NIST guidance on this matter as discussed above, and NIH has consistently concluded that march-in rights may not be exercised for purposes of price control.[73] This abrupt change in approach to permit exercising march-in rights to control prices could result in an unconstitutional taking of a licensee's commercialized inventions.

Second, exercising march-in rights based on an alleged failure to meet a previously absent reasonable pricing standard could create a due process violation under the Fifth Amendment. The due

[66] *Whitman v. Am. Trucking Assns., Inc.*, 531 U.S. 457, 468 (2001).
[67] *MCI Telecomms. Corp. v. American Tel. & Tel. Co*., 512 U.S. 218, 229 (1994).
[68] 35 U.S.C. § 203(a)(1).
[69] *Norvir I* at 5–6.
[70] *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978).
[71] *See, e.g., Ruckelshaus v. Monsanto*, 467 U.S. 986, 1013 (1984) (recognizing that although a company cannot have a reasonable investment backed expectation when the statute and agency are silent, such an expectation arises when the company relies on an established legal framework outlining the government's rights); *see also Lingle v. Chevron U.S.A.*, 544 U.S. 528, 539 (2005) (holding that an appropriation of the property right results in an economic impact).
[72] *King v. United States*, No. 18-1115, 2023 WL 3141796 (Fed. Cl. Apr. 28, 2023) (citing *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 327 (2002)).
[73] *See Xalatan* at 5, *Norvir I* at 5, and *Norvir II* at 6.

process inquiry is one of fairness,[74] and prohibits the deprivation of a property right without clear notice and clear standards for the basis of the deprivation.[75] First, holders of exclusive licenses invest significant funds into bringing drugs to the market with the understanding that they will be able to recoup these investments through competitive pricing; permitting agencies to march in on these exclusive licenses would deprive the license holders of their ability to do so. Second, licensees who entered agreements prior to the Draft Framework had no notice that they would be subject to pricing controls at the time of investment, nor at any time since.[76] Finally, the Framework does not articulate any clear standard to indicate when price may be used as a factor in the march-in analysis, leaving licensees to guess at what price point they may face the deprivation of their exclusive patent rights. Depriving licensees of property for failing to meet an unknown standard is fundamentally unfair and raises due process issues.[77]

In light of significant inventor interests in retaining exclusive property rights and the risk of erroneous deprivation without clear standards by which to judge pharmaceutical pricing, sufficient process requires notice of the applicable pricing control(s) *prior* to a march-in proceeding and guidance on the process by which deprivation of rights would occur.[78] Biopharmaceutical companies should have the opportunity to assess price controls before (1) choosing to invest in the commercialization of subject inventions and (2) making pricing determinations. Although some may argue the Draft Framework provides notice of the consideration of price for future interested parties, the Draft Framework does not involve any clear guidance of the relevant price analysis that would apply if march-in rights were considered by a funding agency on this basis. For all these reasons, the inclusion of price as a factor to consider under criterion 1 is contrary to the Act itself and will lead to outcomes contrary to it.

B. Disregarding its Own Long Held Understanding, NIST Now Inappropriately Injects Price into the March-in Analysis under the Health and Safety Needs Criterion

The Draft Framework also newly and inappropriately injects price as a consideration into criterion 2 for march-in authority, to determine whether a contractor, assignee, or their licensees reasonably satisfies a health or safety need. Under criterion 2, a federal funding agency may determine that march-in "is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees[.]"[79] Unlike criterion 1, in which a definition of practical application is included in the statute, there is no definition provided in the statute of a health or safety need or what it might mean to "reasonably satisfy" one. Yet, in the Draft Framework's analysis of criterion 2, it problematically includes questions as to whether a product's initial price *or* its price after an increase is extreme, unjustified, and exploitative to determine whether a health and safety need has been reasonably satisfied.[80]

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[74] *Hannah v. Larche*, 363 U.S. 420, 487 (1960) (Frankfurter, J., concurring).
[75] *See Mathews v. Eldridge*, 424 U.S. 319, 332, 348 (1976).
[76] A person "in jeopardy of serious loss" must be given "notice of the case against him and opportunity to meet it;" to deny such notice would violate the "essence of due process." *Id.*
[77] *Id*. at 343 ("An additional factor to be considered . . . is the fairness and reliability of the existing pretermination procedures . . ..")
[78] *See Mathews v. Eldridge*, 424 U.S. 319 (1976).
[79] 35 U.S.C. § 203(a)(2).
[80] 88 Fed. Reg. 85599 ("Is the contractor or the licensee exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances?" "For example, has the contractor or licensee implemented a sudden, steep price increase in response to a disaster that is putting people's health at risk? *It should be noted that in reviewing this question, the agency is not limited to reviewing price increases; the initial price may also be considered if it appears that the price is extreme, unjustified, and exploitative of a health or safety need.*" (emphasis in original)).

As a general matter, the Draft Framework does reflect some recognition that the Bayh-Dole Act is intended to be used only in limited circumstances and is not the only tool funding agencies have to address situations that may arise related to subject inventions.[81] Further, the Draft Framework affirms that march-in should not be used to achieve an outcome contrary to the goals of the Bayh-Dole Act, such as "broad and unintended consequences on U.S. competitiveness and innovation."[82] Still, the Draft Framework incorporates novel inquiries on price that seem designed to have such consequences.

The statutory text provides no basis to incorporate price to determine whether a health or safety need has been reasonably satisfied. The history and context of the Act also provides no basis to determine that price should be considered as part of the health and safety criterion. However, as with criterion 1, statements from the Act's sponsors and agency decisions on the issue are much more instructive. First, Senator Bayh expressly rejected the notion of considering prices in the context of health and safety. He stated the following as part of the only public meeting held in connection with a march-in request:

> If it can be shown that the health and safety of our citizens is threatened by practices of a government contractor, then Bayh-Dole permits march-in rights, not to set prices, but to ensure competition and to meet the needs of our citizens. However, such a procedure must be supported by hard evidence that the need exists. Speculative claims and misrepresentation of the legislative history supporting Bayh-Dole will not suffice.[83]

NIH decisions have also rejected the consideration of price when determining whether a health or safety need has been satisfied. NIH has found that health and safety needs have been reasonably satisfied by the contractor or commercializing licensee where a drug product is approved by the FDA as being safe and effective;[84] is prescribed for its approved indications;[85] where there is no indication that the drug is in short supply;[86] or where the manufacturer is working with federal agencies to correct any supply issues if they arise.[87] Similar to practical application, these factors focus on the commercial availability of the drug product in light of federal safety requirements. In its Fabrazyme decision in 2010, NIH established the central inquiry as "whether there is an existing health need of Fabry patients associated with the exclusive licensing [of the subject invention] and whether NIH, by exercising its march-in authority,

[81] *See, e.g., id.* at 85596 ("To date, no agency has exercised its right to march-in. Several agencies have considered march-in previously but have either declined to exercise it or worked with the parties to find an alternative solution to achieve the desired objectives. March-in is an important tool for agencies, but that tool is accompanied by potentially significant positive and negative ramifications.")
[82] *See, e.g., id.* at 85600 (suggesting federal funding agencies should "[c]onsider ways to ensure that any use of march-in achieves the intended outcomes and does not have broad and unintended consequences on U.S. competitiveness and innovation.")
[83] *See* Sen. Bayh Statement, *supra* note 41, at 6.
[84] *See, e.g., Norvir I* at 5 ("Norvir® has been approved by the [FDA] as safe and effective and is being widely prescribed by physicians for its approved indications. No evidence has been presented that march-in could alleviate any health or safety needs that are not reasonably satisfied by [the patent owner]."); *Xalatan* at 5; *Norvir II* at 5. Where a drug product is not yet FDA approved, funding agencies may consider whether the drug is medically necessary or effective.
[85] *See Norvir I* at 5; *Norvir II* at 5.
[86] *See Xtandi* at 1 (noting increasing sales of enzalutamide and that "no information was identified from public sources to suggest that enzalutamide is currently or will be in short supply.").
[87] *See Fabrazyme I* at 6–7.

could alleviate the problem."[88] Within this inquiry, NIH never found that a health and safety need could be met by exercising its march-in rights.

Further, where advocates have sought march-in on the basis of price under criterion 2, NIH has expressly rejected that argument and considered price *separate from* criterion 2. "No evidence has been presented that march-in could alleviate any health or safety needs that are not reasonably satisfied by [the contractor]. Rather, the argument advanced is that the product should be available at a lower price, which is addressed below. Thus, the NIH concludes that [the contractor] has met the statutory and regulatory standard for health or safety needs."[89] NIH's decision has made clear that the price at which the product is offered is not a part of the health or safety need analysis.

Despite this history and NIH precedent, the Draft Framework asks funding agencies to consider: "Is the contractor or the licensee exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances?" and "has the contractor or licensee implemented a sudden, steep price increase in response to a disaster that is putting people's health at risk?"[90] The factual scenarios then go on to debate these questions, without coming to any relevant conclusions, while acknowledging that there could be many instances in which price increases are not a basis for march-in criteria, including that the entire market has experienced similar price increases or in general there exists a "compelling justification."[91] Opening up this new inquiry to consider price in the context of a health and safety need is wholly unsupported by the statutory language, statements from bill sponsors, and the agency decisions on this issue. From a policy perspective, it could also be quite detrimental to public health to seek to control pricing when a health or safety need must be met, as such efforts could discourage needed investment to accelerate development and expanded manufacturing and supply. Perhaps the Draft Framework is seeking to acknowledge this dynamic by stating "a compelling justification" may exist, but such a distinction would be unnecessary had NIST not inappropriately injected price into the analysis in the first instance. NIST's analysis jeopardizes private investment in solutions to reasonably satisfy health and safety needs, without which, the response to urgent health or safety needs would be significantly hamstrung.

In sum, including price in the analysis to determine whether march-in should be exercised under criterion 1 or 2 lacks a basis in the Act and opens up further uncertainty about the proper scope of march-in authority, which will cause negative effects on commercialization and innovation—outcomes NIST has stated it seeks to avoid. PhRMA strongly objects to the inclusion of price in the Draft Framework.

IV. The Draft Framework's References to Price are Unclear and Harmful

Beyond the arguments raised in Section III that incorporating price in the march-in analysis is contrary to Bayh-Dole, including price in the Draft Framework raises additional issues about the meaning of the term "price" that the Draft Framework does not address. The concept of price is exceedingly complex in the biopharmaceutical context as explained below, let alone considering price in the context of countless products across the full range of industries that contract with the Government.

[88] *Fabrazyme I* at 4.
[89] *Norvir I* at 5.
[90] 88 Fed. Reg. 85599.
[91] *Id.* at 85603.

Importantly, the Draft Framework does not discuss or identify numerous important considerations with respect to price,[92] including: who decides or establishes the relevant price, where in the supply chain a price is assessed, and whether the price takes into account reimbursement policies. In criterion 1—practical application—the Draft Framework incorporates questions that may be relevant, such as: "[i]s the contractor or licensee marketing or selling to end-users or consumers in the U.S.? If not, why?" and "Has the product utilizing the subject invention been sold or offered for sale in the U.S. using distribution channels (e.g., retailer, wholesaler, through a regulated intermediary, or direct to consumer) used for similar products?"[93] The Draft Framework, however, does not discuss why it is asking these questions or apply these concepts elsewhere in the Draft Framework. Such distinctions are clearly relevant with respect to price because a price for the same product may vary across end-users or consumers. For instance, in the context of biopharmaceuticals, the ultimate patient consumer may pay different prices based on their health insurance coverage and whether they qualify for various assistance programs.

Further, there are numerous factors in the biopharmaceutical context that impact the prices at which products are available to patients and payors, including federal reimbursement, discount and procurement programs, Pharmacy Benefit Manager (PBM) and private insurer policies, and patient assistance programs. The Draft Framework does not acknowledge any of these highly contextual factors that affect the general concept of "price." However, the complexity of this issue is but one of many reasons wading into the analysis of price in the Draft Framework is wholly inappropriate. As discussed above in Section III, NIST's approach is contrary to the Bayh-Dole Act itself. Moreover, conducting such an analysis without acknowledgement of the corresponding complexities in each industry reflects a reckless disregard for the industries NIST seeks to guide. Ignoring the intricacies of particular industries also ensures that the Draft Framework will be unable to achieve consistent application of the march-in analysis. NIST appears to believe that if the Draft Framework's analysis is made general enough, then the analysis can be assumed to apply consistently across industries. That is simply not the case.

Rather than creating a technology neutral framework that can be consistently applied, NIST has created a Draft Framework that inappropriately targets public-private partnerships and will discourage future commercialization of innovations stemming from such partnerships. Senator Bayh's post enactment statements on pricing reflect his hypothesis that this outcome would arise: "What evidence is there that large drug companies will not simply walk away from collaborations with our public sector? That is what happened to NIH."[94] By incorporating price in the march-in analysis, NIST raises the possibility that not only biopharmaceutical companies but companies in other industries will reconsider collaborations with the public sector as a result.

V. The Draft Framework Creates Other Interpretive Issues

Beyond the quagmire NIST has waded into by incorporating price in the Draft Framework, NIST has also raised new questions regarding the substantial manufacturing criterion of Bayh-Dole and NIST's new term, "shelving." NIST's approach with respect to these two issues reflects a broader concern with the Draft Framework—that consistent application of the march-in rights analysis is difficult, if not impossible, without clear agency-level guidance on key interpretive issues under the Act.

[92] We have identified considerations that are particularly relevant to the biopharmaceutical industry; however, we expect nuances with respect to pricing would arise in other industries too.
[93] *Id.*
[94] Sen. Bayh Statement, *supra* note 42, at 5.

A. NIST Avoids Key Interpretation of the Substantial Manufacturing Criterion

Although Bayh-Dole has always included insufficient domestic manufacturing terms as a basis for exercising march-in rights under Section 203(a)(4), the Draft Framework heightens the focus on criterion 4 without providing any guidance about how to interpret key terms, while signaling the prospect of increased enforcement. As a background summary of criterion 4, i.e. "the substantial manufacturing" criterion, title holders of subject inventions must not "grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States."[95] A federal funding agency may waive this requirement, however, upon a showing "that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible."[96] If "the agreement required by section 204 has not been obtained or waived" or if the exclusive licensee is in breach of the terms of the agreement under section 204, the federal funding agency may exercise its march-in rights.[97]

The Draft Framework discusses the requirements of Section 204 as if the terms of this Section are clear, yet interpretive questions remain about several key terms or phrases, including the meaning of: (1) "embodying", (2) "produced through the use of", and (3) "manufactured substantially." There are no definitive regulations or guidance addressing the meaning of these terms under Bayh-Dole, such that these questions commonly arise as to the scope of the U.S. substantial manufacturing requirement. For example, where a subject invention is only a component of a final product, reasonable arguments can be made that Section 204 does not apply to the manufacturing of the entire product but rather only to the component that the Government has had any involvement in, such that only the component that contains a subject invention embodies such invention but not the entire final product. The Draft Framework, however, does not consider the potential ambiguity that arises when analyzing the extent to which a product embodies a subject invention or is produced through the use of a subject invention, e.g., instances in which the subject invention is a minor fraction of the overall cost to manufacture the product, incidental to the purpose of the product, or part of a combination product.

Because there are no definitive interpretations of the substantial manufacturing requirement, stakeholders have been left to rely on informal guidance and analogous alternate frameworks for assessing compliance with the U.S. substantial manufacturing requirements, without clarity as to what any particular Federal agency considers as the controlling analytical framework for making the assessment. Without a recognition of the status quo of the varying analysis stakeholders perform under this requirement, the Draft Framework is unlikely to achieve its goal to "[e]ncourage the consistent and predictable application of the Bayh-Dole Act's march-in authority,"[98] because the factors that have caused this inconsistent analysis have not been addressed.

Case law in the biopharmaceutical context highlights the persistent ambiguity surrounding the question of whether an end-product is considered to be made in the United States, which stakeholders have considered to inform the substantial manufacturing requirement under the Act. Petitioners in *Acetris Health* sought to establish that a product could be considered substantially transformed, and therefore made in the U.S., because the active pharmaceutical ingredient (API) was converted from bulk to dosage

[95] 35 U.S.C. § 204.
[96] *Id.*
[97] 35 U.S.C. § 203(a)(4).
[98] 88 Fed. Reg. 85594.

form in the United States.[99] No court has yet directly ruled on a new interpretation of substantial transformation (instead, *Acetris Health* was ultimately decided on the interpretation of the Federal Acquisition Regulation's (FAR's) definition of a U.S.-made end product), but these challenges raise the possibility that the focus of the substantial transformation analysis may shift from where the API was initially manufactured to where the API is combined with excipients and converted into a dosage form. Scenario 8 in the Draft Framework, discussed further below in Section VI, makes a reference to the location of the manufacture of the API, but otherwise does not discuss or recognize other factors that may weigh on the substantial manufacturing analysis. Such a vague reference leaves stakeholders to further question the proper application of the substantial manufacturing requirement under the Act.

In the majority of the references to the substantial manufacturing requirement, the Draft Framework appears to focus on whether an exclusive license incorporates a substantial manufacturing requirement, rather than the actual meaning of substantial manufacturing.[100] The Draft Framework could be read as suggesting an analysis of the cost of all components of the product in which the subject invention is incorporated, though the Draft Framework is unclear as to the proper inquiry. In one instance the Draft Framework asks, "[t]aking the manufacturing locations of all components of the product into consideration, would the product be considered to have been manufactured substantially in the U.S.?"[101] The Draft Framework however, does not consider whether factors other than the manufacturing locations of the components are relevant to the analysis or what threshold of manufacturing would lend itself to the conclusion that a product has been manufactured substantially in the United States.

We understand that agencies undertake various interpretations when assessing compliance with this requirement, and yet the Draft Framework does not shed light on these varying interpretations, nor provide guidance as to what framework or frameworks are acceptable. Further, it is especially inappropriate to discuss heightened enforcement of the substantial manufacturing criterion—e.g., in Scenario 8 considering whether exercising march-in "would send a message that the U.S. industry preference provisions of the Bayh-Dole Act will be enforced"—when agencies may vary in their treatment of waiver applications or interpretation of the meaning of substantial manufacturing.[102] Without addressing these nuances, the Draft Framework will not achieve its stated goal to achieve "consistent and predictable application of the Bayh-Dole Act's march-in authority."[103]

B. The New "Shelving" Definition Raises More Questions

The Draft Framework's definitions section generally consolidates definitions found in Bayh-Dole or other relevant statutes, except for one definition, the definition of shelving. "Shelving" appears to be a bespoke term made for the Draft Framework. Under the Draft Framework, shelving means: "[w]hen an entity holds a patent or has a license to make, use, or sell an invention, but they do not develop, use, or

[99] *See Acetris Health, LLC v. United States*, 949 F.3d 719 (Fed. Cir. 2020); *Acetris Health, LLC v. United States*, No. 18-cv-00040-TCS (C.I.T. dismissed Sept. 10, 2020). The *Acetris* decision held that where API for a drug product was produced in India and the product was pressed into its final pill form in New Jersey, the "product" (which it defined as the pill or tablet) (1) is not substantially transformed into tablets in India and (2) is "manufactured" in the United States. *Id.* at 731–32.
[100] *See* 88 Fed. Reg. 85599. ("Did the contractor's exclusive license agreement require that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U.S.?"); *see also id.* at 86504 (discussing in Scenario 8 that "the exclusive license does not include a provision requiring products to be manufactured substantially in the U.S.").
[101] *Id.* at 85599.
[102] *Id.* at 85605.
[103] *Id.* at 85594.

sell that invention (or a product embodying the invention) or seek out third parties to do so for an extended period of time."[104] The concept of shelving is incorporated into the practical application criterion ("Are there concerns about the contractor shelving the subject invention(s) without justification and not committing to discernable steps on re-engaging in its licensing?")[105] and Scenarios 1 and 2.[106] As a threshold matter, there is no discussion about what would be considered "an extended period of time." Further, the Draft Framework raises the specter of unjustifiable, impermissible, or inappropriate shelving, but does not provide clear guidance on when shelving may be, for instance, justified or unjustified. From a stakeholder perspective, there are a number of reasons a perceived delay in commercialization could be justified, and those reasons are likely to vary significantly across industry. Proposing opportunities for federal agencies to second guess the commercialization and research and product development decisions of private industry is not a purpose of Bayh-Dole, and could risk pressuring companies to complete research and testing quickly to avoid march-in. Companies conducting the necessary research and product development to commercialize subject inventions must be free to make decisions based on their expertise and in the interest of patient health and safety. Language that creates opportunities for federal agencies to second guess these decisions should therefore not be included in the Draft Framework.

Instead, the Draft Framework refers to vague analysis in an effort to reach an undefined conclusion. For instance, in Scenario 1, the Draft Framework suggests an "inquiry to determine if the licensee is inappropriately shelving the technology."[107] As part of this inquiry, the Draft Framework states that "if this is a case of a licensee is [*sic*] impermissibly shelving a subject invention to preserve the market position of a competing product, march-in here could deter similar actions by others in the future."[108] Perhaps the Draft Framework is defining impermissible shelving as preserving the market position of a competing product, but because it does not expressly incorporate this concept into the definition, it appears the applications of shelving are broader than that one instance. Further, this scenario raises exercising march-in rights as a deterrent of impermissible shelving. Bayh-Dole does not contemplate exercising march-in rights as a means to deter future violations of the Act—the relevant consideration is whether a statutory criterion is met or not.

NIST also discusses shelving in a manner that raises questions about its meaning. In Scenario 2, the Draft Framework states that "[t]he first part of this analysis looks at whether march-in would promote utilization and protect against shelving or non-use of this invention[.] Here, it appears the contractor is still actively developing this technology and not shelving it, which would weigh against march-in, even though other licensees might also be able to bring this technology to market."[109] NIST confusingly discusses non-use in addition to shelving, though use (or non-use) is incorporated in the shelving definition. NIST should clarify whether shelving and non-use are distinct concepts or whether non-use is encompassed under the shelving definition.

NIST specifically seeks feedback on whether "the definitions provided at the beginning of the framework [are] easy to understand? Do they aid in your ability to interpret the framework?"[110] In the instance of shelving, the key gaps in the definition discussed above reduce the definition's usefulness to aid in the interpretation of the Draft Framework. The Draft Framework appears to rely on the scenarios to

[104] *Id.* at 85595.
[105] *Id.* at 85598–99.
[106] *Id.* at 85601–02.
[107] *Id.* at 85601.
[108] *Id.*
[109] *Id.* at 85602.
[110] *Id.* at 85595.

provide anecdotal examples of the meaning of shelving, though the scenarios themselves raise additional questions about the term's meaning and lack utility as they do not come to conclusions on key issues.

VI. The Factual Scenarios Cause Further Confusion and Uncertainty

The Draft Framework concludes with eight factual scenarios that are intended to "showcase how an agency might apply this framework, considering certain factors and questions, in assessing march-in."[111] However, the scenarios do not come to any conclusions; rather they appear to consider worst-case scenarios, leaving open the possibility for an agency to come to any possible conclusion. The scenarios are also subject to other weaknesses. A fundamental, limiting factor of the scenarios is that they cannot encompass the "the totality of circumstances in a real-life situation," rather they are engineered to highlight certain facts.[112] Although NIST warns that "nothing in the discussions of these scenarios should be interpreted as an obligation upon the agency to exercise march-in," the scenarios give credence to consideration of certain facts, such as price, that would allow agencies to make determinations inconsistent with the Act's purpose.[113]

The assumptions incorporated in the scenarios further limit their applicability to real-world circumstances. Notably, the Draft Framework limits the scenarios to instances in which "[o]nly Bayh-Dole subject inventions are needed to successfully manufacture the product (i.e., no additional intellectual property licensing or access to non-patent proprietary know-how or trade secrets would be needed)."[114] Such scenarios are of limited utility to agencies and stakeholders, because they do not account for the vast majority of subject inventions that are incorporated in commercialized products. For instance, a 2019 study found that only one percent of drugs, i.e. two of 197, in the Orange Book were covered only by patents that had Bayh-Dole disclosures or were assigned to a government entity.[115] The Draft Framework recognizes that march-in rights will be of limited use where more than one subject invention is incorporated in the product: "For example, if only one of several patents necessary to produce a product is subject to march-in, that likely weighs against march-in, since other licensees would need separate permission to use several other patents before they could make the product."[116] Based on the Draft Framework's own assessment, then, march-in rights are unlikely to have much, if any, practical impact in the vast majority of cases, while at the same time potentially preventing innovation on a much broader scale.

Certain scenarios raise the possibility that competitor companies interested in manufacturing a subject invention will petition the funding agency to grant it a license to the subject invention.[117] Although the Draft Framework acknowledges there are limits to a competitor's ability to successfully

[111] *Id.* at 85601.
[112] *Id*.
[113] *Id*.
[114] *Id.*
[115] *See* Barnett Letter, *supra* note 30, at 8 (referencing Genia Long, *Federal Government-Interest Patent Disclosures for Recent Top-Selling Drugs*, 22 J. MED. ECON. 1261, 1265 (2019)).
[116] 88 Fed. Reg. 85600.
[117] *See, e.g.*, Scenario 1, *id.* at 85601 ("A second company has approached both parties for a license to the university-owned patent, but its request was denied, so the second company has asked the government funding agency to march-in and require the university to grant it a license to the university patent."); Scenario 2, *id.* ("A large, established construction company is looking to launch a 3–D printing initiative and it has asked the government funding agency to march-in and grant it a license to the startup's patent portfolio.")

petition an agency to exercise its march-in rights,[118] at the same time, the Draft Framework problematically encourages a competitor's attempts to use march-in rights to assert that it can commercialize a product faster or cheaper than the patent holder or licensee by free-riding on the significant technical and financial risks taken and investment made by the licensee.[119] Therefore, the Draft Framework creates a potential incentive to abuse march-in rights, which are intended as a remedy only in extraordinary circumstances, as a tool to harass competitors. As discussed in Section III.A.1, these extraordinary circumstances would apply only when a company has not taken, or does not *expect to take*, "steps to achieve the practical application" of the subject invention.[120] March-in rights should not be a mechanism for potential competitors to argue they could better commercialize a subject invention than the contractor, assignee, or licensee. Notwithstanding that such an interpretation is contrary to the Act, even if the march-in request is ultimately denied, an entity subject to a march-in rights request may be necessarily required to expend significant resources to combat such requests that are beyond the statute's purpose, which would disincentivize other private entities from making substantial and risky investments in early-stage discoveries.

Senator Bayh discussed that: "Congress must keep in mind that the vast majority of technologies developed under the law are commercialized by small companies that 'bet the farm' on one or two patents. Copycat companies are always waiting until an entrepreneur has shown the path ahead. They can always make things cheaper since they have no significant development costs to recover."[121] Raising the possibility that competitors could successfully march-in on companies developing new technology as Senator Bayh described, creates risks that such companies will either choose not to collaborate with a public entity or not pursue the technology at all. Further, Senator Bayh's concern does not only apply to small companies. Well-established biopharmaceutical companies invest significant resources—including time, talent, and funds—to bring nascent technology to market, often exponentially more than the initial federal investment. If competitors are permitted to free-ride off of this significant private investment based on an unclear standard of march-in criteria, established companies will be significantly disincentivized from making the necessary investment to bring the technology to market in the first instance.

Further, certain criteria are given short shrift in the scenarios such that their proper interpretation remains unclear. Only one scenario considers criterion 4 and only in the context where the exclusive license agreement did not include the agreement terms required by 35 U.S.C. § 204.[122] The scenario alludes to facts that might be considered under a substantial manufacturing analysis, e.g., that the exclusive licensee has manufactured limited quantities of the API of the compound at its existing facilities in Switzerland.[123] However, the scenario does not conduct an inquiry into what factors might weigh on whether a product was substantially manufactured in the U.S. Further, considering this scenario only in the biopharmaceutical context will do a disservice to other industries in which the API concept is not relevant. Still, open questions remain regarding the proper treatment of the API within the country of origin analysis under the Trade Agreements Act, which causes uncertainty under the Bayh-Dole Act as well. By not considering whether substantial manufacturing has been achieved, and rather focusing on whether the exclusive license holds the relevant requirements, the scenario misses an opportunity to

[118] *See, e.g.*, Scenario 2, *id.* at 85602 ("The mere fact that a potential competitor might be able to bring a subject invention to market more quickly than the contractor does not mean the contractor is impermissibly shelving a subject invention.").
[119] *See supra* notes 117, 118.
[120] 35 U.S.C. § 203(a)(1) (emphasis added).
[121] Sen. Bayh Statement, *supra* note 10, at 5.
[122] *Id.* at 85604.
[123] *Id.*

provide insight into, or at least recognize, the appropriate inquiry. Instead, it appears the Draft Framework skirts the hard interpretive questions that stem from the ambiguity of the statute.

The need to create such a vague analysis identifies a fundamental problem with the Draft Framework—that NIST is not well-positioned to provide such broad guidance. We note that three of the eight factual scenarios address the biopharmaceutical industry (Scenarios 1, 4, and 8), although the Draft Framework is intended to be technology-neutral. The Draft Framework ignores certain industries and agencies that contribute to a significant amount of federal funding to research. In recent years, eight agencies have made up 97% of total R&D funding—the Department of Defense, Department of Health and Human Services, Department of Energy, National Aeronautics and Space Administration, National Science Foundation, Department of Agriculture, Department of Commerce, and Department of Veterans Affairs.[124] However, the scenarios are not representative of those agencies or the technologies developed with their funding, and is instead overly focused on biopharmaceuticals and medical devices. This is yet another reason why the Draft Framework and corresponding scenarios have little hope of providing the type of broad guidance and consistency NIST promises.

VII. Conclusion

As stated throughout our comments, the Draft Framework is contrary to the text and the goals of Bayh-Dole and could reverse the exponential gains seen in commercialized inventions since the passage of the Act in 1980. The Draft Framework seeks to make march-in a more accessible agency tool, yet exercising march-in rights is intended as an extraordinary remedy. The fact that march-in rights have never been exercised is not a problem that needs to be solved—it is a reflection of the success of the Act to incentivize commercialization of subject inventions. Exercising march-in rights is not a solution to the policy issues that the Administration and Congress have failed to address, such as the out-of-pocket costs of healthcare for U.S. consumers. Thus, for at least the reasons presented in these comments, PhRMA encourages NIST to withdraw the Draft Framework. We appreciate the opportunity to provide comments on the Draft Framework and stand ready to engage more extensively with NIST as to interpretation of march-in rights and of the Bayh-Dole Act more generally.

Respectfully submitted,

/s/	/s/
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[124] *See, e.g.*, CONG. RSCH. SERV., R47564, Federal Research and Development (R&D) Funding: FY2024 4 (May 19, 2023), https://crsreports.congress.gov/product/pdf/R/R47564.